QUALITY ASSURANCE

The quality assurance (QA) program at the West Valley Demonstration Project (WVDP or Project) provides for and documents consistency, precision, and accuracy in collecting and analyzing environmental samples and in interpreting and reporting environmental monitoring data.

Organizational Responsibilities

West Valley Nuclear Services Co. (WVNSCO) is contractually obligated to implement a QA program at the WVDP. Managers of programs, projects, and tasks are responsible for determining and documenting the applicability of QA requirements to their activities and for implementing those requirements. For example, the Project Environmental Laboratory management and staff are directly responsible for carrying out sampling and analytical activities in a manner consistent with good quality assurance practices and for following approved procedures.

Program Design

The quality requirements of rule 10 Code of Federal Regulations (CFR) Part 830.122, Quality Assurance Criteria (U.S. Department of Energy [DOE]), and DOE Order 414.1A, Quality Assurance (DOE, 2001) provide the QA program policies and requirements applicable to activities at the WVDP.

The integrated quality assurance program applicable to environmental monitoring at the WVDP also incorporates requirements from Quality Assurance Program Requirements for Nuclear Facilities (American Society of Mechanical Engineers [ASME] NQA-1, 1989) and Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (American National Standards Institute and American Society for Quality Control [ANSI/ASQC E4-1994], 1994).

The QA program focuses upon assigning responsibilities and upon thorough planning, specification, control, and documentation of all aspects of an activity to ensure the quality of both radiological and nonradiological monitoring data. The quality assurance program includes requirements in the areas listed below.

Responsibility. Responsibilities for overseeing, managing, and conducting an activity must be clearly defined. Personnel who verify that the activity has been completed correctly must be independent of those who performed it.

Planning. An activity must be planned beforehand and the plan followed. All activities must be documented. Similarly, purchases of any equipment or items must be planned, specified precisely, and verified for correctness upon receipt.

Control of Design, Procedures, Items, and Documents. Any activity, equipment, or construction must be clearly described or defined and tested. Changes in the design must be tested and documented. Procedures must clearly state how activities will be conducted. Only approved procedures may be used. Equipment or particular items affecting the quality of environmental data must be identified, inspected, calibrated, and tested before use. Calibration status must be clearly indicated. Items that do not conform to requirements must be identified and separated from other items and the nonconformity documented.

Documentation. Records of all activities must be kept in order to verify what was done and by whom. Records must be clearly traceable to an item or activity.

Corrective Action. Conditions adverse to quality shall be promptly identified and corrected. The cause of a problem must be identified, a corrective action planned, responsibility assigned, and the problem remedied.

Audits. Scheduled audits and assessments must be conducted to verify compliance with all aspects of the QA program and determine its effectiveness.

Subcontractor laboratories providing analytical services for the environmental monitoring program are contractually required to maintain a QA program consistent with WVNSCO requirements. They provide analytical data reports and any supplementary documentation necessary to validate the data.

Procedures

Those activities that affect the quality of environmental monitoring data are conducted according to approved procedures that clearly describe how the activity should be performed and what precautions are to be taken in connection with the activity. Any person performing an activity that could affect the quality of environmental monitoring data must be trained and must demonstrate proficiency in procedures applicable to the activity.

New procedures are developed each time an activity is added to the monitoring program. Procedures are reviewed periodically and updated when necessary. Documents are controlled so that only current procedures are used.

Quality Control in the Field

Quality control (QC), an integral part of quality assurance, is used to verify that sample analysis and collection are consistent and repeatable. QC methods are applied in the laboratory (analytical or laboratory QC) and in the field (field QC).

To ensure that samples are collected correctly, appropriate sampling procedures are followed for each type of sample being collected. For example, sample locations at the WVDP are clearly marked in the field to ensure that future samples are collected in the same locations; collection equipment in place in the field is routinely inspected, calibrated, and maintained; and automated sampling stations are kept locked to prevent tampering and to ensure sample integrity. Samples are collected into certified pre-cleaned containers of an appropriate material and capacity. Containers are labeled immediately with the pertinent information – date, time, person doing the collecting, and special field sampling conditions. Collection information is documented and kept as part of the record for that sample.

Chain-of-custody protocols are followed to ensure that samples are controlled and tracked for traceability. If necessary, samples are preserved as soon as possible after collection.

To assess quality problems that might be introduced by the sampling process, duplicate field samples, field blank samples, and trip blank samples are collected. Background samples are collected for baseline environmental information.

Field Duplicates. Field duplicates are samples collected from the same matrix in the same manner at the same time and place. When processed and analyzed identically, but as independent samples, they provide information on sample homogeneity and sampling precision. Field duplicates are collected at frequencies specified in applicable sampling plans.

Field Blanks. A field blank is a sample of laboratory-deionized water that is put into a sample container at a field collection site and is processed from that point as a routine sample. Field blanks are used to detect contamination that may be introduced by the sampling procedure or the sampling environment. They are processed at a minimum rate of one per 20 samples.

If samples are collected with non-dedicated sampling equipment, the laboratory-deionized water is poured over the collection equipment and into the sample container. This type of field blank is called an equipment blank.

Trip Blanks. Trip blanks are prepared by pouring laboratory-deionized water into sample bottles in the laboratory. The bottles are then placed into sample coolers where they remain throughout the sampling process. Trip blanks are collected to detect any volatile organic contamination that may be introduced from handling during collection, storage, or shipping. Trip blanks are prepared once per day when volatile organic samples are being collected.

Environmental Background Samples. To monitor each pathway for possible radiological contamination, samples of air, water, vegetation, meat, and milk are taken from locations remote from the site for comparison with samples from near-site locations. Samples that are clearly outside site influence show ambient radiological concentrations and serve as backgrounds or "controls," another form of field quality control sample. Background samples are collected at the same frequencies, as are samples from their counterpart near-site locations and provide baseline information to compare with information from near-site or on-site samples so that site influences can be evaluated.

Quality Control in the Laboratory

More than 13,500 samples were handled as part of site monitoring in 2003. Samples for routine indicator radiological analysis were analyzed on-site, with the rest being sent to subcontract laboratories.

Off-site subcontract laboratories must maintain a level of QC as specified in contracts with WVNSCO and are required to participate in all applicable crosscheck programs and to maintain all relevant certifications.

To monitor the accuracy and precision of data, laboratory QC practices specific to each analytical method are clearly described in approved references or procedures. Examples of laboratory QC activities at the WVDP include proper training of analysts, maintaining and calibrating measuring equipment and instrumentation, and processing samples in accordance with specific methods as a means of monitoring laboratory performance.

Analytical instruments and counting systems are calibrated at specified frequencies, and logs of instrument calibration and maintenance are kept. Calibration methods for each instrument are specified in procedures or in manufacturers' directions. Standards traceable to the National Institute of Standards and Technology (NIST) are used to calibrate counting and test instrumentation.

Laboratory quality control samples consist of three general types: standards (including spikes), used to assess accuracy; blanks, used to assess the possibility of contamination; and duplicates, used to assess precision.

Standards. A standard is a material having a known property that can accurately be established based upon its physical or chemical characteristics. Standards are usually NIST-traceable materials or standard reference materials of known quantity or concentration.

At a minimum, one reference standard is analyzed for every 20 sample analyses. The results of the analyses are plotted on control charts, which specify acceptable limits. If the results lie within these limits, then analysis of actual environmental samples may proceed and the results are deemed usable.

Spikes. Another form of standard analysis is a laboratory spike. In a spike, a known amount of analyte is added to a sample (matrix spike) or blank (blank spike) before the sample is analyzed to assess percent recovery. The percent recovery of the analyte indicates how much of the analyte of interest is being detected in the analysis of actual samples; hence, a spike also is an assessment of the accuracy of the method. Spike recoveries are recorded on control charts with documented acceptance limits.

Blanks. Laboratory blanks, also called method blanks, are prepared from a matrix similar to that of the sample, but known to contain none of the analyte of interest. For instance, deionized water, taken through the same preparatory procedure as a sample, may serve as a blank for both radiological and chemical analyses of water samples. A positive result for an analyte in a blank indicates that something is wrong with the analysis and that corrective action should be taken. In general, one laboratory blank is processed daily or with each batch of samples for a given analyte.

The instrument background count for radiological samples, a count taken of a planchet or vial containing no sample, is another form of laboratory blank. The count serves three purposes: to determine if contamination is present in the counting instrument; to determine if the instrument is responding in an acceptable manner; and to determine the background correction that should be applied when calculating radiological activity in certain samples.

Environmental samples containing little or no radioactivity must be measured with very sensitive instruments. For example, gross alpha and gross beta measurements must be made with a low-background proportional counter. An instrument background count is taken before each day's counting or with each batch of 20 samples. Background counts are recorded on control charts with defined acceptance limits. An unacceptable count requires corrective action before analyses can proceed.

Duplicates. Laboratory duplicates are created by splitting existing samples before analysis and treating each portion as a separate sample. Laboratory duplicates are used to assess precision in the analytical process.

To allow independent determination of environmental monitoring data, samples of air filters, water, milk, fish, vegetation, and sediments are split or separately collected and sent to the New York State Department of Health (NYSDOH) for measurement and independent reporting to the public. Co-located samples are listed in Appendix B^{C} of this report.

Crosschecks. Crosscheck samples contain a concentration of an analyte known to the agency conducting the crosscheck. However, the concentration is unknown to the participating laboratory. Crosscheck programs provide an additional means of testing accuracy of environmental measurements. WVNSCO participates in formal crosscheck programs for both radiological and nonradiological analyses.

Radiological. The DOE recommends that all organizations performing radiological analyses as part of effluent or environmental monitoring participate in the semiannual Environmental Measurements Laboratory Quality Assessment Program. This program is designed to test the quality of environmental measurements being reported to the DOE by its contractors.

Crosscheck samples for radiological constituents are analyzed by the on-site Environmental Laboratory and by a subcontract laboratory in accordance with contractual requirements. A total of 113 radiological crosscheck analyses were performed by or for the WVDP and reported in 2003. All but three of those results (97.4% overall) were within acceptance limits.

Results from radiological crosschecks are summarized in Appendix J^{C}, Tables J-1 and J-2^{C}.

The Environmental Laboratory analyzed and reported 34 samples in 2003; all results (100%) were within control limits. General Engineering Laboratory submitted 79 results, of which 76 (96.2%) were within control limits.

Nonradiological. Analytical laboratories must demonstrate evidence of satisfactory analytical performance on samples provided by the NYSDOH Environmental Laboratory Approval Program (ELAP). The laboratory must also participate in U.S. Environmental Protection Agency (EPA) Discharge Monitoring Report-Quality Assurance performance evaluation studies. Analytical procedures are to be consistent with the principles and methodologies in 40 CFR Part 136, Methodology, Chemical Analysis of Water and Waste, EPA-600/4-79-020, EPA as updated, or methods cited in the NYSDOH-ELAP manual.

Two nonradiological crosscheck samples (from Environmental Research Associates) for the National Pollutant Discharge Elimination System Discharge Monitoring Report-Quality Assurance Study #23 were analyzed for pH and residual chlorine by the WVDP wastewater facility laboratory in 2003.

Twenty-one crosscheck analyses were performed by Severn Trent Laboratories, an off-site vendor laboratory, for additional parameters in 2003. Nonradiological crosscheck results are summarized in Appendix J^{C}, Table J-3^{C}.

Results from both samples analyzed at the WVDP were within acceptance limits (100%). Of the 21 results reported by the vendor laboratory, 20 were within acceptance limits (95.2%). Combining WVDP and vendor results for nonradiological crosschecks, 97.7% were within control limits.

WVNSCO subcontracted laboratories are required to perform satisfactorily on crosschecks, defined as at least 80% or more of results falling within control limits. Crosscheck results that fall outside control limits are addressed by formal corrective actions to determine any conditions that could ad-

versely affect sample data and to ensure that actual sample results are reliable.

Personnel Training

Anyone performing environmental monitoring program activities is trained in the appropriate procedures and qualified accordingly before carrying out the activity as part of the site environmental monitoring program.

Recordkeeping

Control of records is an integral part of the environmental monitoring program. Field data sheets, chain-of-custody forms, requests for analysis, sample-shipping documents, sample logs, bench logs, laboratory data sheets, equipment maintenance logs, calibration logs, training records, crosscheck performance records, data packages, and weather measurements, in addition to other records, are maintained as documentation of the environmental monitoring program.

Records pertaining to the environmental monitoring program are also maintained electronically. A laboratory information management system (LIMS) is used to log samples, print labels, store and process data, track QC samples, track samples, produce sampling and analytical worklists, and generate reports. All records pertaining to the program are routinely reviewed and securely stored and, for electronic records, routinely backed-up.

Chain-of-Custody Procedures

Chain-of-custody procedures are used to trace sample possession from time of collection through analysis and maintain the appropriate documentation. Chain-of-custody records begin with sample collection. Samples brought in from the field are transferred under signature from the sampler to the sample custodian and are logged at the sample receiving station, after which they are stored in a sample lockup before analysis or shipping. Samples sent off-site for analysis are accompanied by an additional chain-of-custody/analytical request form. Subcontract laboratories are required by contract to maintain internal chain-of-custody records and to store the samples under secure conditions.

Audits and Appraisals

The New York State Department of Environmental Conservation performed an inspection of WVDP's wastewater treatment facilities and State Pollutant Discharge Elimination System (SPDES) discharge monitoring program in 2003. The inspection resulted in no reported findings or observations.

Self-Assessments

Two routine self-assessments of the environmental monitoring program were conducted in 2003. The primary topics addressed by the first assessment were worker safety, QA, trend analysis, and incident reporting. Topics addressed in the second assessment were data validation and sample preservation.

No findings or observations were noted. (See *finding* and *observation* under *self-assessment* [p. GLO-11].) Recommended actions were proposed to improve the program. Nothing was found during the course of these routine self-assessments that would compromise the reliability of the environmental monitoring program in general or the quality of the data in this report.

Lessons Learned Program

Lessons learned data from audits, appraisals, and self-assessments are shared internally and externally through the WVDP lessons learned program.

The WVDP maintains this system in order to promote the recurrence of desirable events or to prevent the recurrence of undesirable events.

Data Management

The laboratory information management system is a database system used for maintaining the sample data log, tracking samples, managing field and analytical data, and recording status and results of data validation. The LIMS is used as a controlled-source database for generating reports and evaluations of data sets to support environmental surveillance activities. Subcontract laboratories are asked to, where possible, provide data in electronic form for direct entry into the LIMS by WVDP personnel.

All software packages used to generate data are verified and validated before use. All analytical data produced in the Environmental Laboratory at the bench level are reviewed and signed off by a qualified person other than the one who performed the analysis. A similar in-house review is contractually required from subcontractor laboratories.

Data Verification and Validation

The data validation process is used to generate validated summary data, including technical qualifications or limitations of these data as based upon regulatory and contract-compliance criteria. Analytical data from both on- and off-site laboratories are reviewed to verify proper documentation of sample processing and data reporting, and to determine the quality and usability of the data. A graded approach is applied that, based upon data quality objectives, dictates the rigor of sample collection and/or sample analysis review. In the WVDP environmental program, each data point is validated per approved standard procedures before it is assigned approval status and made available to the end user.

Control measures, such as chain-of-custody and sample identification numbering and collection dates, are checked to ensure that the correct sample has been analyzed using the appropriate test procedures. The analytical process log information may be reviewed to verify the number and accuracy of quality-check samples and tests. Other quality requirements, such as meeting minimum testing sensitivity and precision levels, are checked for the data being examined.

If the contractually-defined data package deliverables are not met, the data may be either flagged as estimated (useful, for example, as supporting information) or as rejected (not-to-be-used) data. When a sample does not provide a valid data point and analytical or calculation errors cannot be identified and corrected, a retest is often requested on either a remaining sample portion or a similar sample.

After validation is complete, the approved data package contains all of the data from the data generator as well as the qualifier codes affixed to results, where applicable, thereby making the data ready for assessment.

Data Assessment and Reporting

Validated radiological and nonradiological analytical data, field information, and historical project data are integrated and evaluated to assess the specific data usability in determining presence or absence of analytical constituents and, if present, the levels of the constituents. Data problems identified at this level are further investigated and appropriately resolved.

Data from the environmental monitoring program are then processed to assess the effect, if any, of the site on the environment and the public. Data from each sampling location are compared to historical results from the same location, comparable background measurements, and (if applicable) regulatory or guidance standards.

• Radiological concentrations in liquid effluent releases or air emissions are compared with DOE derived concentration guides (DCGs) for release of water or air to an unrestricted environment. DCGs for specific radionuclides are listed in Table K-1C.

• Calculated doses from air emissions are compared with National Emission Standards for Hazardous Air Pollutants limits.

• Nonradiological releases from liquid effluents covered by the SPDES Permit are compared with the limits specified in the permit. (See Table C-1AC.)

• Data trends over time are assessed on a monthly basis and identified trends are investigated.

• Near-site radiological results are compared to results from background locations far from the site.

• Results from surface waters downgradient of the site are compared with results from upgradient locations.

• Groundwater monitoring results are compared to background data for each super solid waste management unit and to background data for the north and south plateaus.

Standard statistical methods are used to compare the data. Where possible, the underlying distribution of the data set is assessed before determining the appropriate statistical tests to be used.

Once the data have been evaluated, reports are prepared. Calculations summarizing the data, for instance, summing the total curies released from an effluent point, averaging the annual concentration of a radionuclide at a monitoring point, or pooling confidence intervals from a series of measurements, are made in accordance with formally-approved procedures. Final data are reported as described elsewhere in this report. (See Data Reporting in Chapter 1 [p. 1-4] and the section on Scientific Notation at the back of this report [p. UOM-2].)

Before each technical report is issued, the document, including the data on which the report was based, is comprehensively reviewed by one or more persons who are knowledgeable in the necessary technical aspects of the field of work.

Summary

The multiple levels of scrutiny built into generating, validating, evaluating, and reporting data from the environmental monitoring program ensure that reliable data are reported. The quality assurance elements described in this chapter ensure that environmental monitoring data are consistent, precise, and accurate. The effectiveness of the monitoring program is evidenced by continuing favorable quality assurance assessments.